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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,059	WING, TONG SUN	
	Examin r	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication app ars on th cover she t with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *19-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/29/2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4/2002* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-18 filed on August 6, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, claims 1-18 will be examined.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because citizenship of the inventor is wrong since Hong Kong is a part of People's Republic of China.

Specification

3. The disclosure is objected to because of the following informalities: (1) Figure 3 has item 8. However, the description for Figure 3 (see the specification, page 13, first paragraph) does not mention item 8; (2) Figure 6 has items 14 and Analyte 11. However, the description for Figure 6 (see the specification, page 14, second paragraph) does not mention items 14 and Analyte 11; (3)) Figure 7 has items 8 and 10. However, the description for Figure 7 (see the specification, page 14, third paragraph) does not mention items 8 and 10; (4) Figure 9 has item 10. However, the description for Figure 9 (see the specification, page 15, last paragraph bridging

to page 16, first paragraph) does not mention item 10. Furthermore, Figure 9 and page 15, last paragraph of the specification have one or more sequences with more than 10 nucleotides. However, there is no SEQ ID NO for these sequences; (5) Figure 10 has items 10, 17, 19, 20, and 21. However, the description for Figure 10 (see the specification, page 16, second paragraph) does not mention items 10, 17, 19, 20, and 21. Furthermore, Figure 10 has two sequences (items 19 and 22) with more than 10 nucleotides. However, there is no SEQ ID NO for these sequences; and (6) Figure 11 has items 10, 17, 19, 20, and 21. However, the description for Figure 11 (see the specification, page 16, third paragraph) does not mention items 10, 17, 19, 20, and 21. Furthermore, Figure 11 has two sequences (items 19 and 23) with more than 10 nucleotides. However, there is no SEQ ID NO for these sequences.

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. For example, see lines 20 and 21 in page 26, lines 24 and 25 in page 32 and lines 5 and 6 in page 33. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Sequence Rules Compliance

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Direct the reply to the undersigned.

Claim Objections

6. Claim 11 is objected to because of the following informalities: (1) "solution" in step (a) of the claim should be "a solution" or " solutions"; (2) "(e)" should be "(d)" since there is no step (d) in the claim; (3) a coma should be added after the phrase "before, during or after step (b)" in step (c); and (4) "binding/hybridization" in step (b) should be "a binding/hybridization".

7. Claim 12 is objected to because of the following informalities: change "step (e)" to "step (d)" and delete (d) in line 3 of the claim in order to correspond to the examiner's suggestion made in claim 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 1 and 11 are rejected as vague and indefinite. Claims 1 and 11 are directed to a method of detecting trace quantities of a molecule target by exploiting a specific interaction between the target and two molecular probes. However, there is no molecule target in the content of the claims. Furthermore, since there is no step for detecting trace quantities of a

molecule target in the content of the claims, the goal in the preamble of the claims cannot reach. Please clarify.

11. Claim 1 is rejected as vague and indefinite in view of the phrase "monitoring for an increase in electrical current from one of the electrodes to the other as might occur if said conductive bead is drawn into said gap by said specific interaction" because, from the phrase, it is unclear whether the step "monitoring for an increase in electrical current from one of the electrodes to the other" occurs or does not occur. Furthermore, it is unclear how said conductive bead is drawn into said gap by said specific interaction since there is no such interaction in the content of the claim. Please clarify.

12. Claim 2 is rejected as vague and indefinite because the claim does not describe the relationship between a well between the electrodes recited in claim 2 and a gap between the electrodes recited in claim 1. Please clarify.

13. Claim 4 is rejected as vague and indefinite because the phase "the conductive bead is demagnetized" lacks insufficient antecedent basis since claim 1 does not specify that the conductive bead is in a magnetic field. Please clarify.

14. Claim 5 is rejected as vague and indefinite because it is unclear what is heated to generate said demagnetization. Please clarify.

15. Claim 6 is rejected as vague and indefinite because "the carrier fluid" lacks insufficient antecedent basis since there is no carrier fluid in claim 1.

16. Claim 7 is rejected as vague and indefinite because the phrase "the iron beads" lacks insufficient antecedent basis since there is no iron bead in claim 1. Since claim 3 has iron beads, claim 7 appears to be dependent on claim 3. Please clarify.

17. Claim 8 is rejected as vague and indefinite because the phrase "the probe" lacks insufficient antecedent basis since claim 1 has two probes and it is unclear which probe in claim 1 is "the probe" in claim 8. Please clarify.

18. Claim 9 is rejected as vague and indefinite because it is unclear what it intended. The word "when" in the claim is very confusing because it is unclear whether the claim means that the method of claim 1 is used to detect multiple agents/molecules in a microprocessor-controlled micro-array or not. Please clarify.

19. Claim 10 is rejected as vague and indefinite because it is unclear what it intended. The word "when" in the claim is very confusing because it is unclear whether the claim means that the method of claim 1 is used to assay the concentration of a given substance. Please clarify.

20. Claim 11 is rejected as vague and indefinite in view of step (a). Since an agent to be identified recited in step (a) does not appear in following steps (b), (c), and (e), it is unclear why step (a) requires an agent to be identified. The examiner suggests that applicant change "the specimen" in step (b) to " the specimen or the agent" in order to overcome the rejection. Please clarify.

21. Claim 11 is rejected as vague and indefinite in view of steps (b) and (c). The phrase "a second probe" in step (c) is confusing since there is no first probe in steps (a) and (b) and it is unclear that "bound probes" in step (b) is a first probe or not since "bound probes" appears to be two or more probes. Furthermore, it is unclear that "binding/hybridization" in step (b) and "specific binding/hybridization" in step (c) are identical or not. If "binding/hybridization" in step (b) and "specific binding/hybridization" in step (c) are identical, the examiner suggests that applicant changes "specific binding/hybridization" in step (c) to "the binding/hybridization" . If

"binding/hybridization" in step (b) and "specific binding/hybridization" in step (c) are not identical, the examiner suggests that applicant changes "specific binding/hybridization" in step (c) to "a specific binding/hybridization". Please clarify.

22. Claim 11 is rejected as vague and indefinite in view of the phrase "any electric current between the electrodes" in step (e). From step (e), it appears that the electrodes in claim 11 can generate various types of electric currents. It is unclear that any electric current between the electrodes can mean how many different kinds of electric currents. Pleas clarify.

23. Claim 12 is rejected as vague and indefinite in view of the phrase "adjusting chemistry and/or temperature of the solution to optimize reaction conditions" because it is unclear what means adjusting chemistry of the solution. Does the word "chemistry" means components here? Please clarify.

24. Claim 13 is rejected as vague and indefinite because the phrase "the use" lacks insufficient antecedent basis since a microprocessor has multiple uses. The examiner suggests that applicant change "the use" to "use". Please clarify.

25. Claim 14 is rejected as vague and indefinite because it is unclear that the word "them" means the phrase "its components" or not. Please clarify.

26. Claim 15 is rejected as vague and indefinite because it does not make sense to engineered the method of claim 1 into two or three-dimensional micro-arrays since the two or three-dimensional micro-arrays are products and are not methods. Please clarify.

27. Claim 16 is rejected as vague and indefinite because it unclear what material has duplications or triplications. Please clarify.

28. Claim 18 is rejected as vague and indefinite because there is no verb in the phrase

"should the test result be negative". It appears that the claim is incomplete sentence. Please clarify.

Claim Rejections - 35 USC § 102

29. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

30. Claims 1-3, 7-13, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Park *et al.*, (US Patent Application Publication No: US 2003/0207296A1, priority date: October 9, 2001 from provisional application No: 60/327,864).

This rejection is made in view of ambiguity of claims 1 and 11 (see above rejection under 35 U.S.C 112, second paragraph).

Park *et al.*, teach nanoparticles having oligonucleotides attached thereto and uses therefor. Figure 68 (see attached Figure 68) showed a selective binding event between a capture oligonucleotide strand located between two electrodes and a target oligonucleotide in solution. As shown in Example 32, first, microelectrodes (60 nm Au on 5nm Ti) with 20 μm gaps were prepared by standard photolithography on a Si wafer with 1000 angstrom coating of SiO_2. The exposed SiO_2 of the entire chip was modified with succinimidyl 4-[malemidophenyl]-butyrate (SMPB) using literature methodology . Capture oligonucleotide strands (4 different alkylthiol

modified oligonucleotides) were immobilized onto the activated surface by spotting in the electrode gaps by manual pipetting to form a DNA chip array. The DNA chip arrays were designed to evaluate the discrimination of the complementary pair, A:T (X=A), from the three single-base mismatches, T:T (X=T), C:T (X=C), or G:T (X=G) in a synthetic 27-base oligonucleotide target. After spotting capture oligonucleotides in the electrode gaps, the chip was stored in a humidity chamber for 24 h allowing the coupling reaction between the SMPB and alkylthiol capped DNA to take place. Second, target DNA and nanoparticle probes were added the gaps to hybridize with the capture oligonucleotide strands and then treated with a silver enhanced solution comprising $AgNO_3$ and hydroquione. After a 3 minute treatment with silver enhancer solution, the gaps with the four different oligonucleotide capture strands exhibited gap resistances larger than 500 MΩ (see page 77). Finally, after a stringency wash of the chip with 0.01 M PBS at room temperature, the resistance values across the electrode gaps were measured using a Fluke 189 multimeter. The resistance of the gap with the perfectly complementary capture oligonucleotide strand (X=A) significantly decreased with silver deposition while all three gaps functionalized with the mismatched capture oligonucleotide strands (X=T, G, or C) remained insulating, even after 20 minutes of enhancing time (see page 77, right column and page 78, left column).

Regarding claims 1 and 8, since Park *et al.*, teach to attach oligonucleotides to gold nanoparticles (see Example 1 in page 45 and left column in page 46) and use nanoparticle probes for the hybridization (see page 77, left column), Park *et al.*, disclose attaching one of said molecule probes (ie., the nanoparticle probe) to a conductive bead (ie., the nanoparticle) as recited in claim 1. Since Park *et al.*, teach that capture oligonucleotide strands (4 different

alkylthiol modified oligonucleotides) are immobilized onto the activated surface by spotting in the electrode gaps by manual pipetting to form a DNA chip array (see page 77, left column) and claim 1 is "comprising" claim that can have two or more probes, Park *et al.*, disclose fixing the other of said probes (ie., 4 capture oligonucleotide strands) in a gap between two electrodes as recited in claim 1. Since, after the hybridization, the resistance values across the electrode gaps are measured using a Fluke 189 multimeter (see page 77, right column) and it is known that V (voltage)= I (current)×R (resistance), the process that measures the resistance values across the electrode gaps must apply an electric potential to said electrodes as recited in claim 1. Since Park *et al.*, teach that the resistance of the gap with the perfectly complementary capture oligonucleotide strand (X=A) significantly decreases with silver deposition while all three gaps functionalized with the mismatched capture oligonucleotide strands (X=T, G, or C) remain insulating, even after 20 minutes of enhancing time (see page 78, left column), significant decrease of the resistance of the gap with the perfectly complementary capture oligonucleotide strand (X=A) indicates that the target DNA and the nanoparticle probes hybridize with the perfectly complementary capture oligonucleotide strand and do not hybridize with the mismatched complementary capture oligonucleotide strands as recited in claims 1 and 8. Since it is known that V (voltage)= I (current)×R (resistance) and significant decrease of the resistance of the gap with the perfectly complementary capture oligonucleotide strand (X=A) indirectly indicates an increase in electrical current, Park *et al.*, disclose indirectly monitoring for an increase in electrical current from one of the electrodes to the other as recited in claim 1 by measuring decreasing of resistance of the gap between two electrodes.

Regarding claim 2, since the gap between two microelectrodes is 20 μm and the gap forms a hole between two electrodes (see page 77, left column and Figure 68), claim 2 is anticipated by Park *et al.*.

Regarding claim 3, since Park *et al.*, teach that nanoparticles used in their assay include metal, semiconductor and magnetic colloidal material (see page 21, left column, last paragraph) and it is known that iron is a metal, claim 3 is anticipated by Park *et al.*.

Regarding claim 7, since Park *et al.*, teach that , if the nucleic acid is present, the circuit between the electrodes should be closed because of the attachment of the nanoparticles to the substrate between the electrodes (see page 32, left column), claim 7 is anticipated by Park *et al.*.

Regarding claims 11 and 13, since Park *et al.*, teach that all the oligonucleotides used in Example 32 are prepared by automated solid phase syntheses (see page 77, left column), Park *et al.*, disclose preparing an agent to be identified (ie., an oligonucleotides) as recited in step (a) of claim 11. Since Park *et al.*, teach that capture oligonucleotide strands (4 different alkylthiol modified oligonucleotides) are immobilized onto the activated surface by spotting in the electrode gaps by manual pipetting to form a DNA chip array and teach to attach oligonucleotides to gold nanoparticles (see Example 1 in page 45 and left column in page 46) and use nanoparticle probes for the hybridization (see page 77, left column), Park *et al.*, disclose introducing the specimen (ie., capture oligonucleotide strands) into a detecting device including a gap between two electrodes wherein the gap contains bound probes as recited in step (b) of claim 11 and adding a second probe that is bound to an electrically conductive bead (ie., the nanoparticle probe) and allowing for specific binding/hybridization to occur as recited in step (c) of claim 11. Since Park *et al.*, teach that the resistance of the gap with the perfectly

complementary capture oligonucleotide strand (X=A) significantly decreases with silver deposition while all three gaps functionalized with the mismatched capture oligonucleotide strands (X=T, G, or C) remain insulating, even after 20 minutes of enhancing time (see page 78, left column), significant decrease of the resistance of the gap with the perfectly complementary capture oligonucleotide strand (X=A) indicates that the target DNA and the nanoparticle probes hybridize with the perfectly complementary capture oligonucleotide strand and do not hybridize with the mismatched complementary capture oligonucleotide strands as recited in step (e) of claim 11. Since it is known that V (voltage)= I (current)×R (resistance) and significant decrease of the resistance of the gap with the perfectly complementary capture oligonucleotide strand (X=A) indirectly indicates an increase in electrical current, Park *et al.*, disclose determining if binding of the conductive bead (ie., the nanoparticle) to the gap h as occurred by indirectly detecting a change in an electrical current between the electrodes as recited in claim 11 by measuring decreasing of resistance of the gap between two electrodes. Since an array taught by Park *et al.*, comprises microelectrodes, claim 13 is anticipated by Park *et al.*.

Regarding claims 10 and 12, since Park *et al.*, teach that a skilled artisan need to adjust the salt solution to achieve a proper cationic concentration in order to find suitable of the salt and buffer components in the stringency wash solution (see page 44, fourth paragraph), claims 10 and 12 are anticipated by Park *et al.*.

Regarding claims 9 and 15, since this system taught by Park *et al.*, is based upon conventional microelectrodes, it is useful for massive multiplexing through the use of larger arrays of electrode pairs than the four used in this Example 32 (see page 78, left column), the method taught by Park *et al.*, is capable of detecting multiple agents/molecules in a

microprocessor-controlled micro-array (ie., an array comprising microelectrodes taught by Park *et al.*,) and forming two or three dimensional micro-assays as recited in claim 15 (see Figure 68 and page 77, left column).

Therefore, Park *et al.*, teach all limitations recited in claims 1-3, 7-13, and 15.

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

32. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park *et al.*, (October 9, 2001) as applied to claims 1, 3, 7-13, and 15 above, further in view of

The teachings of Park *et al.*, have been summarized previously, *supra.* In Example 32, Park *et al.*, do not disclose to physically and/or chemically reducing a cell to its components as recited in claim 14. However, Park *et al.*, do teach that the nucleic acid to be detected is isolated by known methods (see page 23, right column, third paragraph). Since it is known that known nucleic acid isolation methods includes steps of breaking cells and releasing components of the cells, Park *et al.*, disclose that isolation of the nucleic acid to be detected is by breaking cells and releasing components of the cells.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have prepared a specimen having the nucleic acid to be detected recited in claim 11 using the method step recited in claim 14 in view of the patents of

Park *et al.*. One having ordinary skill in the art would have been motivated do so because using nucleic acids from different sources as a specimen in the method recited in claim 11 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because the replacement of one kind of nucleic acid from another kind of nucleic acid as a specimen in the method recited in claim 11 would not change the experimental method steps.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Conclusion

33. No claim is allowed.

34. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
November 7, 2003

part of the office action

FIG. 68